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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,967	05/04/2001	Emanuel Calenoff	21417/92378	6936

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,967

Applicant(s)

CALENOFF ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-16 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 17-19, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



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DETAILED ACTION

Applicant's amendment filed on 4/25/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

Claims 1-3, 17-19 and 21-22 are under examination. Claims 4-16 and 20 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-3, 17-19, 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, step (e), "the part of the comparative" is vague and indefinite. It is suggested that applicant change to "comparative protein" for clarity.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
2. Claims 1-3, 17-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rose et al. (WO 97/12042),

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Rose teach a plurality of immunogenic peptides of a target protein, i.e. Glass III of glycoprotein B which is associated with gamma herpes virus subfamily. The peptides, RGMTEAA and RGLTESA, comprise the following structure:

- a). 7 amino acids in length;
- b). sequence is identical to a contiguous amino acid peptide region of the sequence of the target Class III protein;
- c). a net hydrophilic structure located on the surface of the target protein;
- f). an antigenic profile which elicits an immune response for the target protein (Glycoprotein B class III of herpes virus recognition).

Please see Table 8, Class III, Sequence RGMTEAA and RGLTESA (page 47).

With respect to features of (d) and (e) concerning “comparative protein”, the Office considers the prior art inherently possess the characteristics in comparison to “A” comparative (non-target) protein (emphasis added).

The production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art. See In re Kind, 207 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143, 144-145 (CCPA 1938); In re Bergy, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

“[E]ven though product-by-process claims are limited by and defined by the process,

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determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) [PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical.]

While "indirect comparisons, based on established scientific principles, can validly be applied to distinguish a claimed chemical process or product from that disclosed in the prior art," *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 432 (CCPA 1977), the comparisons must be scientifically valid.

Patent owner's burden under the circumstances presented herein was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . .

Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

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It is noted that the so-called “comparative protein” is vaguely, or alternatively broadly, defined in the specification: any “non-target” protein is a “comparative protein” (See Section 0010 and Section 0012). Additionally, the current invention is a product claim directing to a plurality of immunogenic peptides, *not a comparative protein* (emphasis added). It would be inherent for Rose et al. reference containing the recited feature of (d) and (e) with respect to “A” non-target comparative protein (e.g. a comparative protein not related to herpes virus). Furthermore, it is the burden of applicant to show that the reference of Rose et al. does not possess the recited features of ANY comparative protein compared to the plurality of immunogenic peptides taught by Rose et al. (Note, please see examiner’s response to applicant’s argument below).

With respect to claims 17-19 and 21, Rose et al. teach using the polypeptides as anti-microbial therapeutic agents and coupled with adjuvant molecules which promotes immunogenicity to produce antibodies (See page 50, last paragraph to page 52, last paragraph).

3. Claim 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Malorny et al. (J Bacteriology 1998 Vol. 180, page 1323).

Similarly, Malorny et al. teach a plurality of peptides of Opa target proteins of *Nisseria* associated with the adherence or invasion of *meningitides*, *Nisseria gonorrhoeae* (See Introduction, page 1323, left column).

The peptides contain the recited features, including-

- a). 5-7 amino acid in length (See Table 2, Mab, 210/G9 and 192/B8)
- b). identical to the target protein in part
- c). a net hydrophilic structure located on the surface of the target protein (See Figure 4)
- f). an antigenic profile elicits an immunoresponse (antigenic for patient with gonorrhea, page 1323, left column)

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Under the same reasoning as described above, the plurality of peptides taught by Malorny et al. inherently possess the characteristics of feature (d) and (e) of claim 1 compared to "A" non-target comparative protein. The burden is on applicant to show that there is NO comparative protein with respect to the plurality of peptides disclosed by Malorny et al (emphasis added).

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Geysen et al. (US 5595915).

Similarly, Geysen et al. teach a plurality of peptides for identifying A-type foot and mouth disease virus (FMDV) protein. The peptides have the following characteristics-

- a). 6 amino acids in length;
- b). sequence is identical to a contiguous amino acid peptide region of the sequence of the target A-type FMDV protein (See Example 2; GDLGSI and DLGSIA);
- c). a net hydrophilic structure located on the surface of the target protein;
- f). an antigenic profile which elicits an immune response for the target protein (epitope recognition).

Under the same reasoning, Geysen et al. reference inherently possesses the recited characteristics compared to "A" comparative protein.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. in view of Michael et al. (US 4469677).

Rose et al. reference has been discussed but is silent in teaching prescribing the peptide as a desensitizing agent for therapy purposes. Michael et al. review a conventional method of administering identifying antigen to the host to *desensitize* the nature of an antigen-specific response and incrementally increasing the dosage to induce immune tolerance for more efficient treatment (Col. 1, last paragraph to Col. line 15)(emphasis added).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Rose et al. with the desensitizing method as taught by Michael et al. in order to reduce the immune tolerance, decrease side effects and toxicity, and maximize the expected results.

Response to Applicant's Arguments

8. Applicant's arguments with respect to claims 1-3, 17-19, 21-22 have been considered but are moot in view of the new ground(s) of rejection.

Comparative Protein

As detailed in this Office Action, examiner stresses the essence of the instant invention is a “product” claim, directing to a plurality of immunogenic polypeptides, not any fragment or part of a non-target “comparative protein.” Although the novelty of the “process” remains to be determined, it is the “product” claims under this examination.

Examiner has established that recited prior arts, including Rose, Malonry and Geysen et al. teach a plurality of immunogenic peptides capable of functioning to produce antigenic profile. It is the burden of applicant to show that “NONE” of a non-target “comparative protein” can meet the recited limitation. Taken the Meola et al. reference as a “non-target” comparative protein since the HbsAg is for hepatitis (non-target compared to herpes virus (Rose et al.), or foot-mouth disease (Geysen et al.)), one ordinary skill in the art would find out that the limitation of comparative protein are satisfied. For instance, see below

Target protein	R	G	M	T	E	A	A		
Target protein	R	G	L	T	E	S	A		
Comparative protein Meola et al. reference	K	T	C	T	T	P	A		
Net sequence homology				yes			yes		

In view of the comparison table, the comparative protein, HbsAg, satisfies claim 1 (d) and (e) because the net sequence homology is less than 50% and the matching of the comparative

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protein to the target protein is of some degree. Further, there are no more than three contiguous amino acids are identical to contiguous amino acids of the target protein compared to that of the comparative protein.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

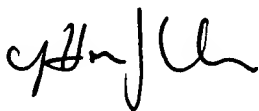
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641



June 27, 2005



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07/05/05